

REMARKS/ARGUMENTS

Claims 1-16, 20-22, 26, 64-65, and 67-78 are pending in the present application and remain rejected. The Examiner considers Applicants' arguments in the previous response to be moot in view of a new ground of rejection, which the Examiner issued with a final rejection.

Telephonic Interview Summary

In a telephonic interview on April 1, 2003, Applicants' representative Melissa L. Sistrunk requested from the Examiner that the finality of the Action be removed in light of new art being cited by the Examiner, but the Examiner refused her request, stating that similar grounds for rejection were at issue. Applicants respectfully disagree but thank the Examiner for his time and consideration during the interview.

Removal of Finality of Office Action

In MPEP 706.07(a), it states the following:

"...second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is **neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c)** with the fee set forth in 37 C.F.R. §1.17(p)." (emphasis added)

Applicants submitted the Information Disclosure Statement (IDS) including U.S. Patent No. 5,676,700 on August 31, 2000, and the mailing date of the First Action was on July 24, 2001. Therefore, the information was not submitted in an IDS during the period set forth in 37 C.F.R. §1.97(c). Furthermore, amendments to the claims made by Applicants were not directed to the issue of the rejection, the cross-sectional configuration of the particle, as even the original claims stated that the cross-section was circular.

Thus, Applicants reiterate that the finality of the rejection is improper and continue to request the Examiner remove its final status.

Applicants kindly request the Examiner consider the following from MPEP §706.07:

"...present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her

application.”

However, Applicants file this Response in a manner responsive to a Final Office Action to further the prosecution of this case.

Issues under 35 U.S.C. §102(b)

Claims 1, 4, 9, 20, 21, 26, 64, 67, 69, 70, and 75-77 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Black et al. (U.S. Patent No. 5,676,700; “Black”). Applicants respectfully disagree.

Black both plainly states and illustrates that the cross-sectional configuration for the extremities is oval. That is, in column 2, lines 57-67, Black clearly states that the cross-sectional configuration is an oval, and this is reiterated in column 3, lines 33-38 and claim 4. Furthermore, Applicants assert that FIG. 2 (the oval shape looking down the center axis of the extremity pointed into the page) and, more particularly, FIG. 7 plainly illustrate the oval cross-section of the extremities. Black even suggests that the oval cross-sectional configuration is an advantage for the invention, “...enhancing the ability of the posts...to enter the inter-post spaces...and attain meshing and interlocking of the structural elements...in the desired tight relationship” (col. 3, lines 33-38).

The Examiner states that Black teaches a circular cross-section in FIG. 1. This figure provides merely a schematic representation having an “elevational view” (col. 2, line 22) of the particle, and therefore one cannot discern the cross-sectional shape of an extremity; in as such, the figure gives an inaccurate perspective. FIG. 7 states it is a true cross-sectional view” (col. 2, line 36) of an extremity of the particle, and this figure clearly shows an oval cross-section. Moreover, all of the relevant discussion in the patent refers to an oval cross-section and never teaches *nor suggests* a circular cross-section, and a skilled artisan in reading the figures in light of the specification would understand that the cross-section is oval and not circular. This is particularly true since the description of the figures and the figures themselves, such as FIG. 2 and FIG. 7 do not teach or suggest a circular cross-section. Applicants assert that FIG. 1 provides an indistinct representation of the extremities with the oval cross-section, because it is seen in the perspective of looking down upon the particle, and the reading of the other figures in light of the specification would be inconsistent otherwise.

Applicants assert that in FIG. 1 it is not possible to ascertain whether the cross-

sectional area is circular or ellipsoidal because of the perspective; it is absolutely necessary to look along the axis of one of the arms to determine if the cross-section is a circle or an ellipse. This view is provided in FIG. 7 and also is provided schematically in FIG. 2, where the length to height ratio of the arm (imagine it protruding from the page) is approximately 1.6:1.1 (*i.e.* an ellipse, or 1.45:1). Therefore, Black definitely does not teach a circular cross-section of the extremities.

A claim is anticipated only if each and every element as set forth in the claims is found in the reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, Applicants assert that Black does not anticipate claim 1 and its dependent claims, 26 and its dependent claims, and claims 75-77 because it does not teach the element of a circular cross-section. Applicants request removal of this rejection.

Issues under 35 U.S.C. §103(a)

Claims 5, 6, 10-13, 22 and 68 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black et al. in view of Chen et al. (U.S. Patent No. 6,180,606; “Chen”). Claims 5-8, 71, and 72 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Barralet (Biomaterials, 1993; “Barralet”). Claims 14-16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Kondo et al. (JP 171546; “Kondo”). Claims 2, 3, 73, 74, and 78 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black in view of Sheppard et al. (WO 94/08912; “Sheppard”). Claim 65 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Black. Applicants respectfully disagree with all of these rejections.

Applicants respectfully assert that the cited claims are not obvious in light of Black by itself or in combination with any of the other references. Black by itself or in combination with other references fails to contain or suggest all of the elements of the pending claims. That is, as stated above, Black fails to teach or suggest having a circular cross-sectional configuration. To establish a *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In light of this criteria, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. §103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

Furthermore, Applicants assert that Black teaches away from the present invention,

and therefore any combination of references with Black would also teach away from the present invention. Black teaches away from the circular transverse configuration by teaching the oval cross-section configuration. That is, Black clearly demonstrates the oval embodiment (col. 2, lines 57-67; FIG. 2; FIG. 7) and moreover states that at least in part that there are advantages of having an oval cross-sectional configuration (col. 3, lines 33-38), which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner might contend.

Applicants strongly assert that Black as a whole teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). The oval cross-sectional shape of the Black structural elements and the indication that they are preferred and confer an advantage to the invention would, therefore, teach away from the circular cross-sectional configuration of the present invention. Thus, Applicants assert that Black teaches away from the present invention, indicating that the pending claims are, in fact, not obvious. Therefore, all of the 35 U.S.C. § 103 rejections over Black are improper, and Applicants respectfully request that the rejections be removed.

Furthermore, regarding the rejection over Black in view of Chen, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 2, Black fails to teach the claimed materials for the particles or composite materials. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Chen to achieve Applicants' claimed invention, and Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Barralet, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach ceramic as gypsum or the array to have a porosity between about 40%-80%. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Barralet to achieve Applicants' claimed invention, and Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Kondo, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach the particle diameter being in the range of about 6mm. Applicants assert there is no suggestion

or motivation for one of skill to combine Black and Kondo to achieve Applicants' claimed invention, and Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Sheppard, Applicants assert that in addition to Black teaching away from the invention Sheppard also teaches away from the present invention, and therefore the combination of these references could not be obvious. As acknowledged by the Examiner in a previous Action, Sheppard does not disclose a circular transverse cross-section configuration. In fact, Sheppard teaches away from the circular transverse configuration by teaching the square cross-section configuration. That is, Sheppard compares the advantages of a square cross-section over a circular cross-section, which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner contends. On Page 12, L33-34, Sheppard states: "... (3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point based coordination of spherical and random shapes..."

In addition to teaching away from the circular cross-section of Applicants' invention, the nature of Sheppard is a clear departure from the present invention, which would lead a skilled artisan in the field in a dissimilar direction. Applicants respectfully direct the Examiner's attention to the previously filed Declaration Under 37 C.F.R. §1.132 of Dr. Ed Margerrison.

Applicants reiterate that Sheppard adumbrates on Page 12, Lines 13-19 that there may be embodiments where the aggregates are not packed into a "zero matrix", but the majority of Sheppard does, in fact, teach that the design of the arms in Figures 5 and 6 is to increase the strength by nesting tightly and providing 0% void volume. Furthermore, the essence of the entire reference teaches that the purpose of the aggregate or array of particles as per Figures 5 and 6 is to increase the strength of a composite material with the array being surrounded by a matrix material.

Sheppard teaches that the composite is likely to have an increased strength and fracture toughness compared with other means of reinforcing composite structures. The array as shown in Figures 5 and 6 has essentially no open porosity within the structure, owing to the extremely highly reticulated structure that the "StarJack" shape gives. That is, it is mentioned that the arrangement described in Sheppard can often be achieved by mixing a number of those granules and applying vibration through *e.g.* mechanical or ultrasound

means. With minimal vibrational forces, the particles of Sheppard regularly pack, and the circular cross-section of the particles of the present invention would not allow this. In fact, the advantage of the circular cross-section of the present invention is to reduce the potential for forming this reticulated structure so that a number of the individual granules together will retain an open interconnected porosity. The shape of the Sheppard granules described in the vast majority of the reference would, therefore, teach away from the configuration of the present invention.

For example, on Page 7, Line 1 Sheppard states, “One aspect of the present invention is an aggregate having a unique three-dimensional shape theoretically capable of packing to 100% density without any void volume.....” The particles of the present invention cannot pack to 100% density, nor would such density be desirable for treating a bone deficiency (an element of Claim 1).

Also, on Page 12, Line 2 it states, “As shown by Figs. 4-6, this property permits the aggregates to be arranged in a nesting configuration, wherein faces of one aggregate are disposed adjacent faces of neighboring aggregates in a regular array.

Applicants expand the above citation of the following passage on Page 12 from Sheppard:

“We believe the Starjack, Tetratwin and Tetrastar represent novel classes of aggregate shapes with reticulate geometries marked by, for example:

- (1) The ability of same-class components of equivalent volume to nest uniformly;
- (2) Improved architectural properties of the nesting pattern itself (reticulate matrix), which may be varied in its thickness dimension in accordance with application demands;
- (3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point-based coordination of spherical and random shapes or the line-to-line based coordination of fibrous reinforcements;
- (4) Substantially increased potential for crack path tortuosity.... (emphasis added)”

As described in the previously filed affidavit, Applicants assert that one skilled in the art would not recognize that the array of particles of the present invention illustrated in Figure 2 in the instant specification are in a “nested” array. Instead, one skilled in the art interprets the term “nested” to mean “to pack compactly together,” and in the context of the teachings of Sheppard for flat surfaces of the arms in a “plane-based coordination”, the packing would be so compact as to teach away from the bone deficiency-treating configuration of the array as taught by the Applicants.

Thus, Applicants reiterate that for multiple reasons Sheppard teaches away from the present invention, and therefore the combination with Black, and this indicates that the pending claims are, in fact, not obvious.

Applicants also submit that the rejections under 35 U.S.C. §103(a) for Black alone and in combination respectively with Chen, Barralet, Kondo, and Sheppard are each an application of an “obvious to try” standard in the field of shaped bone particles. For Black, the reference teaches a oval cross-sectional configuration and the advantages therewith, and although Applicants strongly assert this teaches away from the present invention, Applicants also suggest the Examiner is improperly citing an obviousness rejection wherein the rejection is more accurately an “obvious to try” rejection. The “obvious to try” standard has been held to constitute an improper ground for a 35 U.S.C. § 103 rejection. *In re O’Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An “obvious-to-try” situation exists when a general disclosure may pique an inventor’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Similarly, Black does not teach Applicants invention, and although the Examiner alleges the particles in Black are obvious, Applicants assert the oval cross-sectional configuration of the particles teach away from the present invention, and the rejection is in fact an “obvious to try” rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please

charge our Deposit Account No. 06-2375, under Order No. HO-P01952US0 from which the undersigned is authorized to draw.

Dated:

April 16, 2003

Respectfully submitted,

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